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Equipment performance specifications and test procedures

E01: Cold rooms and freezer rooms

VACCINES AND BIOLOGICALS
WORLD HEALTH ORGANIZATION

This module contains references to the following documents:

WHO/V&B/02.34: Guidelines for establishing or improving primary and intermediate vaccine stores
WHO/V&B/00.13: Product Information Sheets (2000 Edition)

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Abbreviations

°C	Degrees centigrade
CFC	Chlorofluorocarbon
dB	Decibels
EPI	Expanded Programme on Immunization
hrs	Hours
Hz	hertz
IEC	International Electrotechnical Commission
Incoterms 2000	International Chamber of Commerce commercial delivery terms
ISO	International Standards Organization
K	Kelvin
kg	Kilograms
kVA	kilovolt-ampere
kW	kilowatts
kWh	kilowatt-hours
m	Metre
m2	Square metres
m3	Cubic metres
mm	Millimeters
PC	Personal computer
PIS	WHO/UNICEF Product Information Sheets
PQS	Performance, Quality and Safety
ITS-90	International Temperature Scale of 1990
UNICEF	United Nations Childrens' Fund
W	Watts
WHO	World Health Organization

Introduction

1.1 Cold rooms and freezer rooms

Cold rooms and freezer rooms are normally used to store vaccines at the national or sub-national level for periods of several months. If a cold room or freezer room fails, the immunization services of an entire country may be placed at risk. Consequently, equipment must be specified, installed and maintained to the highest available standards.

This document outlines specifications for step-in and walk-in units with a capacity of up to about 40m^3 capacity. It should be modified to suit individual cases. Cold rooms and freezer rooms that are significantly larger should only be specified in consultation with a refrigeration specialist.

1.2 Equipment descriptions

The performance specifications given in this document apply to the following types of rooms suitable for storing vaccines:

E01/CR/FR-2.1 Cold rooms (+2°C to +8°C) and freezer rooms (-15°C to -25°C)

1. How to buy and maintain cold rooms and freezer rooms

Unlike other cold chain equipment, cold rooms and freezer rooms are purpose made and have to be assembled and commissioned on site. The buyer is responsible for selecting a space for the room and for preparing this space so as to make it suitable for the installation. The building housing a cold room needs to be accessible, in good condition, have suitable finishes, have adequate ventilation, and be fitted with the correct electricity supply.

The stages involved in buying and commissioning a cold room are summarised below. For further details refer to WHO/IV&B/02.34: *Guideline for establishing or improving primary and intermediate vaccine stores, WHO/IV&B/04.16-20 WHO-UNICEF Effective Vaccine Store Management Initiative Modules 1-4* and other relevant sources.

1. **Decide location and capacity:** Decide the location and required capacity of the cold room(s) and freezer room(s). Select the spaces(s) in which the equipment is to be installed.
2. **Shortlist suppliers:** Contact cold room suppliers and establish which are able to provide, install, commission and service cold rooms and freezer rooms conforming to these specifications. Prepare a tender list of at least three companies. Although WHO does not endorse any particular manufacturers, a list of suppliers with relevant experience is given in WHO/EPI/V&B/00.13: the *Product information sheets (2000 edition.*
3. **Prepare and invite tenders:** Prepare tender documentation using the model specifications contained in this document, and invite tenders. At the same time, tenders may be invited for standby generators, if these are needed. Guidance on specifying and buying generators is given in WHO/EPI/V&B/00.13: Product information sheets (2000 edition).
4. **Place order:** Receive and evaluate tenders, agree an installation programme, and place an order with the winning supplier.
5. **Prepare the site:** Prepare the space for the cold room in accordance with the supplier's requirements and the guidance set out in the reference documents.
5. **Supervise:** Supervise the installation and oversee commissioning and user training.
6. **Monitor:** Monitor the performance of the equipment in use and monitor the effectiveness of the maintanence agreement.
7. **Renew:** Ensure that the maintenance agreement is renewed after the expiry of the initial contract.

2. How to use this document

This document serves as PQS Standard E01/CR/FR-2.1 for equipment and acceptance testing as well as providing a tendering document. Standards are prescribed requirements such as specific temperature ranges. A required on-site test procedure is provided and can serve as a post-installation acceptance test. Tendering support is written in a way that the user may customize requirements that are not prescribed.

There are numerous cross references between the standard clauses in the specifications which follow. In order to avoid confusion, users should strike through any inapplicable clauses but should not change the clause number.

4. Cold rooms operating at +2°C to +8°C

CR.1 **Type of equipment**: Cold room(s) for storing bulk vaccine.
Location of installation: As clause CR.6, and in accordance with the further details referred to in clause CR.7.
Number and size of units: As clause CR.6.
Delivery terms: <*Term*> (Incoterms 2000) <*destination or port of entry*>.

GUIDANCE NOTE: Specify the required Incoterms and point of delivery.

CR.2 **Quality control standards:** Component manufacture and all installation and commissioning processes must be in accordance with ISO 9001.

GUIDANCE NOTE: The current version is ISO 9001:2000, but certification to ISO 9001:1994 should be acceptable.

CR.3 **Information to be submitted with tender:**
Submit the following supporting information with the tender documents (ignore any clauses that have been deleted):
Technical details:
- Plans, elevations and sections at 1:50 scale showing each cold room, its refrigeration equipment and the shelving layout proposed.
- Method statement describing proposed shipment and assembly procedures (CR.25).
- Details of any builders work to be carried out by the purchaser, including any requirements for permanent ventilation, heating or cooling in the space(s) housing the cold room(s)
- Programme for manufacture, delivery and erection.
- Evidence of ISO 9001 certification (CR.2).
- Full technical details of all incorporated components and equipment, including panel construction, shelving, refrigeration units and refrigerant, alarm system (including dB rating of sounder), temperature monitoring equipment and proposed consumables and spare parts.
- Details of voltage stabilizer, if required (CR.21)
- Evaporator area.
- Details of oil separator (if condenser located outside).
- Power consumption data (CR.10).
- Electrical safety certifications for all components (CR.11).
- Details of the proposed spare parts and consumables inventory (CR.22 andCR.23).
- Details of proposed training programme(s) (CR.26).
- Details of the proposed maintenance service and of the local maintenance agent, together with specific proposals for routine and emergency maintenance (CR.27).
- Anticipated empty weight of the complete installation(s) in kilograms.

Tender details:
- Specify delivery time.
- Specify warranty terms
- Specify shipping details, including packed weight and volume.
- Price for supplying the specified components to the site(s), including payment terms and currency.
- Price for installing and commissioning the components, including payment terms and

currency.
- Price for supplying the spare parts, including payment terms and currency.
- Price for training users, including payment terms and currency.
- Price for training repair technician(s), including payment terms and currency.
- Estimated annual cost of consumables.
- Cost of five year maintenance agreement, including payment terms and currency.

CR.4 **Temperature control**: Cold room temperature must remain between +2°C to +8°C when measured in any part of the room, under any loading condition between empty and full design limits, and over the full ambient temperature range specified in CR.5.

CR.5 **Climatic conditions:** The temperature control set out in CR.4 is to be achieved under the following climatic conditions:

Hot zone: maximum continuous ambient summer temperature +43°C and minimum continuous ambient winter temperature 0°C.
OR
Temperate zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature 0°C.
OR
Cold zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature -10°C.

GUIDANCE NOTE: Select one climate regime only and strike out the descriptions that do not apply. Alternatively, specify the actual temperature regime derived from national climate data. In cold climates, pay particular attention to the selection of the worst- case minimum winter temperature. For example, is the room in which the cold room is to be located permanently heated, and will this heating be 100% reliable? If not, then low temperature protection is essential.

CR.6 **Capacity and location:** The cold room(s) and shelving layout(s) must be sized to accommodate the volume(s) of vaccine set out in the table below. Cross-refer to clause CR.16.

Unit Ref.	Location	Maximum stored volume (litres)

GUIDANCE NOTE: Calculate and insert required net storage volume for each cold room. Make sure you know the type of packaging in which the vaccine is to be stored - e.g. intermediate packaging, or insulated shipping containers. Choosing the latter will greatly increase the required size of the cold room.. If vaccine is stored in shipping containers shelving may not be needed as the vaccine can be stacked on pallets. Include the volume of any other items that are to be stored in the cold room. Make a generous allowance for future needs – for example, new vaccines in smaller presentations, integrated services.

CR.7 **Location details:** Install cold room(s) in the locations(s) indicated on the worksheet(s) and drawing(s) attached to this specification. Details of the location(s) are shown on the drawing(s).

GUIDANCE NOTE: For each location, complete the worksheet at the end of this document and provide a dimensioned drawing.

CR.8 **Control by thermostat:** Cold room temperature must be controlled by a thermostat within the tolerances specified in clause CR.4. The thermostat must be calibrated to ITS-90 and be accurate to ± 0.5°C or better. NOTE: Industry reviewers please suggest specified location(s) of sensor(s).

CR.9 **Holdover time:** In the event of power failure, the **c**old room temperature must remain above +2° C at the specified minimum ambient operating temperature, or below +10° C at the specified maximum ambient operating temperature, for at least 8 hours.

CR.10 **Power consumption:** Confirm the following for each cold room:

- The maximum starting current per phase.
- The maximum running current per phase.
- The estimated annual energy consumption in kW/hrs.based on the climatic conditions at the specified site.

Low power consumption is a factor in selecting equipment.

CR.11 **Electrical safety rating:** At time of tendering confirm the national or international electrical safety standards to which each incorporated electrical and electronic component is manufactured and installed. Must comply with IEC 60335-1 Household and similar electrical appliances-safety.

CR.12 **Panel insulation:** Foam insulation must be CFC-free. In cold zones (per CR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m²K or better. In temperate zones (per CR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.20 W/m²K or better In hot zones (per CR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.17 W/m²K or better.

CR.13 **Panel construction:** Panels must be made from hot-dip galvanized steel sheet, fully insulated, without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed to minimize cold-bridging. Gaskets must be resistant to damage from oil, fats, water and detergents. Floor panels must have a hard-wearing non-slip finish. Wall and roof panels must have a white plastics coating.

CR.14 **Door construction:** Doors must be insulated to same standard as clause CR.12. Doors must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of door must be 600mm minimum for rooms up to 10 cubic metres and at least 800 mm minimum for larger rooms. Provide an internal clear plastic strip curtain.

OPTION: Provide a door frame heating element.

GUIDANCE NOTE: A door frame heating element is recommended in humid climates.

CR.15 **Shelving:** Provide **w**all-mounted or free-standing stove enameled steel, galvanized steel,

stainless steel, or aluminium slatted adjustable shelving units to carry vaccine in packages. Slatted shelves are preferred. Shelves must be not less than 450 mm and not more than 600 mm deep at approximately 450 mm vertical centres. The lowest shelf must be mounted 200mm above the floor. Each shelf must be rated to support at least 2 kg/cm². The span between vertical supports must be 1 meter or less.

CR.16 **Refrigeration units:** Provide packaged refrigeration units with single-phase or three- phase compressors, sized to give 100% stand-by capacity under worst-case conditions. There must be a timer operated electric or hot-gas defrosting system and a condensate drip tray and drain connection. Provide an automatic duty-sharing circuit with seven-day changeover and manual override in event of mechanical failure. Provide protection against high or low voltage and against cycle fluctuations. There must be an automatic cut-out when conditions are outside the cold room manufacturer's defined safe limits and an automatic cut-in within 6 minutes of the restoration of safe conditions.

Units must be wall-mounted with the condenser unit discharging inside the building that houses the cold room.
OR
1.) Evaporator units must be wall-mounted with a weatherproof condenser unit mounted externally.
OR
2.) The units must be ceiling-mounted with a condenser unit discharging inside the building that houses the cold room.
OR
3.) Evaporator units must be ceiling-mounted with a weatherproof condenser unit mounted externally.

GUIDANCE NOTE: Strike out options which do not apply.

Some vaccines are damaged by exposure to a temperature of -0.5°C. Size the evaporator units so that the plume of discharged air at a temperature below 0°C is clear of shelving units. If necessary provide a removable mesh cage around the evaporator so as to maintain a safe storage zone.

OPTION: Provide a low- temperature protection system to prevent the temperature of the cold room dropping below +2°C under worst-case winter conditions.

GUIDANCE NOTE: Strike out this option only if there is NO risk of the ambient temperature outside the cold room falling below the + 2°C internal minimum specified in CR.4 for periods of more than a few hours. For example, even a hot zone location COULD require low-temperature protection during the winter months.

CR.17 **Refrigerant:** CFC-free to comply with the requirements of the Montreal Protocol. Flammable refrigerants are not acceptable. The casing of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10mm high. The casing of each refrigeration unit should be permanently marked with the WHO/EPI 'CFC-free' symbol, as shown in Annex 1. The symbol must not be less than 100mm in diameter.

CR.18 **Lighting:** Provide an internal ceiling-mounted tungsten filament light fitting with external switch and pilot light. The external light and light switch must be fixed to the wall of the cold room enclosure near to entrance door. NOTE: Fluorescent lighting damages certain vaccines

and must not be used.

CR.19 **Alarm system:** Provide a mains-operated audible alarm with battery backup and automatic recharge, which is triggered in the event of mains failure or when cold room temperatures are outside set limits.

Alarm sounder repeaters to be located in Cold Room and also one remote location.

All alarm systems must comply with PQS E06 equipment specifications.

GUIDANCE NOTE: The alarm sounder must be located where it can be heard. This may not be in the building where the cold room is housed.

CR.20 **Temperature recording:** Provide a programmable electronic temperature and event logger system with auto-dialer to comply with PQS E06/TR03 linked to the alarm system specified in CR 19. Provide a backup dial thermometer to comply with PQS E06/TH02 mounted on the wall of the cold room in an accessible position.
OR
OPTION 2: Provide a 7-day **w**all-mounted pen recording thermometer with a temperature sensor and door-open sensor. The device is to comply with PQS EO6/TR04,
GUIDANCE NOTE: A PC-based system with auto-dialer is now considered essential for national stores and is preferred for all cold room. If no suitable PC is available to run the temperature-logging software, ensure that one is obtained as part of the installation contract. Door-open sensors are desirable, but not essential. Pen recorders are an acceptable alternative for smaller cold rooms located at the intermediate level. They are only acceptable at the primary level as a backup device.
NOTE: Industry reviewers please suggest specified location(s) of sensor(s).

CR.21 **Voltage stabilizer:** Provide protection against high/low voltage and against cycle fluctuations. The cold room manufacturer must provide a voltage stabilizer appropriate to the electricity supply conditions where the store is to be constructed. Voltage stabilizers must comply with PQS E07.

GUIDANCE NOTE: Strike out this clause only if the power supply is sufficiently reliable. If the supply is not reliable, provide tenderers with the information listed in Annex 2 – clause 15.

CR.22 **Consumables:** Provide consumables sufficient for 2 years of normal operation at the specified location(s).

CR.23 **Spare parts:** Provide spare parts sufficient for 5 years of normal operation at the specified location(s).

GUIDANCE NOTE: Spare parts may not be necessary if a service contract is taken out with a local agent. Consider purchasing spare refrigeration unit(s) so as to ensure the maintenance of the integrity of the system in the event of a unit failure. Try to standardize room sizes so that the spares inventory has universal application. Refer to CR.27.

CR.24 **Instructions:** For each cold room provide a user's manual, a workshop manual and an installation guide in the relevant language – Arabic, English, French, Russian or Spanish.

GUIDANCE NOTE: Specify the international language most used in the country.

CR.25 **Installation and commissioning/acceptance test:** Installation and commissioning/acceptance test is to be carried out by the manufacturer, the supplier, or the supplier's appointed agent. Details of the commissioning tests must be recorded and a copy of the test report is to be handed over with instruction manuals.

GUIDANCE NOTE: See Annex 3 for verification protocol.

CR.26 **Training:** Provide an operator's training course lasting not less than four hours and covering all aspects of safe operation and routine non-specialist maintenance of the cold room.

OPTION: Provide a course to train qualified refrigeration technicians in the maintenance and repair of the installed equipment.

GUIDANCE NOTE: Strike out the option if not required. See guidance note to CR.27.

CR.27 OPTION: **Maintenance:** Provide proposals for a routine and emergency maintenance service for an assured period of not less than five years following commissioning. The emergency service must guarantee the following:

- If one refrigeration unit fails the defective unit or component must be repaired or replaced within seven days after the failure is reported.
- If both refrigeration units fail, at least one refrigeration unit must be repaired or replaced within 24 hours after the failure is reported. The second unit must be repaired or replaced within seven more days.
- Ancillary components such as alarms and thermometers must be replaced within seven days after reported failure.

GUIDANCE NOTE: Managers of immunization services MUST ensure that the best available maintenance arrangements are in place for the cold room. Either local refrigeration technicians should be trained as indicated in clause CR.26 or the cold room installer should be contracted to provide a maintenance service similar to that described in clause CR.27. In some countries it is not possible to achieve the response times given in CR27. In such cases, the clause should be modified in consultation with the installer.

5. Freezer rooms operating at -15°C to -25°C

FR.1 **Type of equipment**: Freezer room(s) for storing bulk vaccine.
Location of installation: As clause FR.6 and in accordance with the further details referred to in clause FR.7.
Delivery terms: <*Term*> (Incoterms 2000) <*destination or port of entry*>.

GUIDANCE NOTE: Specify the required Incoterms and point of delivery.

FR.2 **Quality control standards:** Component manufacture and all installation and commissioning processes are to be in accordance with ISO 9001.

GUIDANCE NOTE: The current version is ISO 9001:2000, but certification to ISO 9001:1994 should be acceptable.

FR.3 **Details to be submitted with tender:**
Submit the following supporting information with the tender documents (ignore any clauses that have been deleted):
Technical details:
- Plans, elevations and sections at 1:50 scale showing each freezer room. including its equipment and the shelving layout proposed.
- Method statement describing proposed shipment and assembly procedures (FR27).
- Programme for manufacture, delivery and erection.
- Details of any builders work to be carried out by the purchaser, including any requirements for permanent ventilation, heating or cooling in the space(s) housing the freezer room(s)
- Evidence of ISO 9001 certification (FR.2).
- Full technical details of all incorporated components and equipment, including panel construction, shelving, refrigeration units and refrigerant, alarm system (including dB rating of sounder), temperature monitoring equipment and proposed consumables and spare parts.
- Details of voltage stabilizer, if required (FR.23)
- Evaporator area.
- Details of oil separator (if condenser located outside).
- Power consumption data (FR.10).
- Electrical safety certifications for all components (FR.11).
- Details of the proposed spare parts and consumables inventory (FR.24 and FR.25).
- Details of the proposed training programme(s) (FR.28).
- Details of the proposed maintenance service and of the local maintenance agent, together with specific proposals for routine and emergency maintenance and details of proposed spares inventory (FR.29).
- Anticipated empty weight of the complete installation in kilograms.

Tender details:
- Specify delivery time.
- Specify warranty terms
- Specify shipping details, including packed weight and volume.
- Price for supplying the specified components to the site(s), including payment terms and currency.
- Price for installing and commissioning the components, including payment terms and

currency.
- Price for supplying the spare parts, including payment terms and currency.
- Price for training users, including payment terms and currency.
- Price for training repair technician(s), including payment terms and currency.
- Estimated annual cost of consumables.
- Cost of five year maintenance agreement, including payment terms and currency.

FR.4 **Temperature control**: Freezer room temperature must remain between -25°C to -15°C when measured in any part of the room, under any loading condition between empty and full design limits, and over the full ambient temperature range specified in FR.5.

FR.5 **Climatic conditions:** The temperature control set out in FR.3 must be achieved under the following climatic conditions:

Hot zone: maximum continuous ambient summer temperature +43°C and minimum continuous ambient winter temperature 0°C.
OR
Temperate zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature 0°C.
OR
Cold zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature -10°C.

GUIDANCE NOTE: Select one climate regime only and strike out the descriptions which do not apply. Alternatively, specify the actual temperature regime derived from national climate data.

FR.6 **Capacity and location:** The freezer room(s) and shelving layout(s) must be sized to accommodate the volume(s) of vaccine set out in the table below. Cross-refer to clause FR.17.

Unit Ref.	Location	Maximum stored volume (litres)

GUIDANCE NOTE: Calculate and insert required net storage volume for each freezer room. Make sure you know the type of packaging in which the vaccine is to be stored - e.g. intermediate packaging, or insulated shipping containers. Choosing the latter will greatly increase the required size of the freezer room. If vaccine is stored in shipping containers shelving may not be needed as the vaccine can be stacked on pallets. Include the volume of any other items that are to be stored in the freezer room. Make a generous allowance for future needs – for example, new vaccines in smaller presentations, integrated services.

FR.7 **Location details:** Install freezer room(s) in the locations(s) indicated on the worksheet(s) and drawing(s) attached to this specification. Details of the location(s) are shown on the drawing(s).

GUIDANCE NOTE: for each location, complete the worksheet at the end of this document and provide a dimensioned drawing.

FR.8 **Control by thermostat:** Freezer room temperature must be controlled by a thermostat within the tolerances specified in clause FR.4. The thermostat must be calibrated to ITS-90 and accurate to ± 0.5°C or better. NOTE: Industry reviewers please suggest specified location(s) of sensor(s).

FR.9 **Holdover time:** In the event of power failure the freezer room temperature must remain below -10° C for a minimum period of 8 hours at the specified maximum ambient operating temperature.

FR.10 **Power consumption:** Confirm the following for each freezer room at the time of tendering:

- The maximum starting current per phase.
- The maximum running current per phase.
- The estimated annual energy consumption in kW/hrs based on the climatic conditions at the specified site.

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Low power consumption is a factor in the selection of equipment.

FR.11 **Electrical safety rating:** At time of tender, confirm the national or international electrical safety standards to which each incorporated electrical and electronic component is manufactured and installed. Provide written evidence of compliance. Must comply with IEC 60335-1 Household and similar electrical appliances-safety.

FR.12 **Panel insulation:** Foam insulation must be CFC-free. In cold zones (per FR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m²K or better. In temperate zones (per FR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.20 W/m²K or better. In hot zones (per FR.5) the thermal transmittance (U value) of the roof, wall and floor panels must be 0.17 W/m²K or better.

FR.13 **Panel construction:** Panels must be made from hot-dip galvanized steel sheet, fully insulated, without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed to minimize cold-bridging. Gaskets are to be resistant to damage from oil, fats, water and detergents. Floor panels must to have a hard-wearing non-slip finish. Wall and roof panels must have a white plastics coating.

FR.14 **Pressure relief valve:** Provide a pressure relief valve in the roof.

FR.15 **Door construction:** Doors must be insulated to same standard as clause FR.12. They must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of door must be 600mm minimum for rooms up to 10 cubic metres and at least 800 mm for larger rooms. Provide an internal clear plastic strip curtain. Provide a door frame heating element.

GUIDANCE NOTE: A door frame heating element is essential for freezer rooms.

FR.16 **Heater mat:** Provide an electric resistance heater mat below freezer room floor, with thermostatic control.

GUIDANCE NOTE: Under certain circumstances, a freezer room can freeze the soil under the room floor. Freezing causes the ground to expand and can crack a concrete floor slab. Laying an electric heater mat under the freezer room floor panels eliminates this risk.

A heater mat is also necessary if a freezer room is located on an upper floor, in order to prevent excessive cooling of the structural floor slab and consequent damage from moisture condensation on the ceiling below.

Whether a heater mat is required ultimately depends upon the location of the store, the climatic regime and the size of the freezer room: seek the manufacturer's advice.

FR.17 **Shelving:** Provide wall-mounted or free-standing stove enameled steel, galvanized steel, stainless steel, or aluminium slatted adjustable shelving units to carry vaccine in packages. Slatted shelves are preferred. Shelves must be not less than 450 mm and not more than 600 mm deep at approximately 450 mm vertical centres. The lowest shelf must be mounted 200mm above the floor. Each shelf must be rated to support at least 2 kg/cm². The span between vertical supports must be 1 meter or less.

FR.18 **Refrigeration units:** Provide packaged refrigeration units with single-phase or three-phase compressors sized to give 100% stand-by capacity under worst-case conditions. There must be a timer-operated electric or hot gas defrosting system and an electrically heated condensate drip tray and drain connection. Provide an automatic duty-sharing circuit with seven-day changeover and a manual over-ride to be used in the event of mechanical failure. Position the evaporator units so that the plume of discharged air cannot be blocked by stored vaccine. Provide protection against high or low voltage and against cycle fluctuations. There must be an automatic cut-out when conditions are outside the freezer room manufacturer's defined safe limits and an automatic cut-in within 6 minutes of the restoration of safe conditions.

Units must be wall-mounted with the condenser unit discharging inside building that houses the freezer room.
OR
1.) The evaporator units must be wall-mounted with a weatherproof condenser unit mounted externally.
OR
2.). The units must be ceiling-mounted with the condenser unit discharging inside the building that houses the freezer room.
OR
3.) The evaporator units must be ceiling-mounted with a weatherproof condenser unit mounted externally.

GUIDANCE NOTE: Strike out options which do not apply. (e.g. compressors located in a confined space may overheat, especially in hot climates).

FR.19 **Refrigerant:** CFC-free to comply with the requirements of the Montreal Protocol. Flammable refrigerants are not acceptable. The casing of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10mm high. The casing of each refrigeration unit should be permanently marked with the WHO/EPI 'CFC-free' symbol, as shown in Annex 1. The symbol must not be less than 100mm in diameter.

FR.20 **Lighting:** Provide an internal ceiling-mounted tungsten filament light fitting with external

switch and pilot light. The external light and light switch must be fixed to the wall of the cold room enclosure near to entrance door. NOTE: Fluorescent lighting damages certain vaccines and must not be used.

FR.21 **Alarm system:** Provide a mains-operated audible alarm with battery backup and automatic recharge, which is triggered in the event of mains failure or when freezer room temperatures are outside set limits.

All alarm systems must comply with PQS E06 equipment specifications.

Alarm sounder repeaters to be located in Freezer Room and also one remote location.

GUIDANCE NOTE: The alarm sounder must be located where it can be heard. This may not be in the building where the freezer room is housed.

FR.22 **Temperature recording:** Provide a programmable electronic temperature and event logger system with auto-dialer to comply with PQS E06/TR03 linked to the alarm system specified in CR 19. Provide a backup dial thermometer to comply with PQS E06/TH02 mounted on the wall of the cold room in an accessible position
OR
OPTION 2: Provide a 7-day **w**all-mounted pen recording thermometer with a temperature sensor and door-open sensor. The device is to comply with PQS EO6/TR04,
GUIDANCE NOTE: A PC-based system with auto-dialer is now considered essential for national stores and is preferred for all cold room. If no suitable PC is available to run the temperature-logging software, ensure that one is obtained as part of the installation contract. Door-open sensors are desirable, but not essential. Pen recorders are an acceptable alternative for smaller cold rooms located at the intermediate level. They are only acceptable at the primary level as a backup device.
NOTE: Industry reviewers please suggest specified location(s) of sensor(s).

FR.23 **Voltage stabilizer:** Provide protection against high or low voltage and against cycle fluctuations. The freezer room manufacturer must provide offer a voltage stabilizer appropriate to the electricity supply conditions where the store is to be constructed.

GUIDANCE NOTE: Strike out this clause only if the power supply is sufficiently reliable. If the supply is not reliable, provide tenderers with the information listed in Annex 2 – clause 15.

FR.24 **Consumables:** Provide consumables sufficient for 2 years of normal operation at the specified location(s).

FR.25 **Spare parts:** Provide spare parts sufficient for 5 years of normal operation at the specified location(s).

GUIDANCE NOTE: Spare parts may not be necessary if there is a service contract with a local agent. Consider purchasing spare refrigeration unit(s) so as to ensure the maintenance of the integrity of the system in the event of a unit failure. Try to standardize room sizes so that the spares inventory has universal application. Refer to FR.29.

FR.26 **Instructions:** For each cold room provide a user's manual, a workshop manual and an installation guide in relevant language – Arabic, English, French, Russian or Spanish.

GUIDANCE NOTE: Specify the international language most used in the country.

FR.27 **Installation and commissioning/acceptance test:** Installation and commissioning/acceptance test must be carried out by the manufacturer, the supplier, or the supplier's appointed agent. Details of the commissioning tests must be recorded and a copy of the test report must be handed over with instruction manuals.

GUIDANCE NOTE: See Annex 3 for verification protocol.

FR.28 **Training:** Provide an operator's training course that lasts not less than 4 hours, covering all aspects of safe operation and routine non-specialist maintenance of the freezer room.

OPTION: Provide a course to train qualified refrigeration technicians in the maintenance and repair of the installed equipment.

FR.29 OPTION: **Maintenance:** Provide proposals for providing a routine and emergency maintenance service for an assured period of not less than 5 years after commissioning. The emergency service must guarantee the following:

- If one refrigeration unit fails the defective unit or component must be repaired or replaced within seven days after the failure is reported.
- If both refrigeration units fail, at least one refrigeration unit must be repaired or replaced within 24 hours after the time the failure is reported. The second unit must be repaired or replaced within seven more days.
- Ancillary components such as alarms and thermometers must be replaced within seven days after reported failure.

GUIDANCE NOTE: Managers of immunization services MUST ensure that the best available maintenance arrangements are in place to look after the freezer room. Either local refrigeration technicians should be trained as indicated in clause FR.28 or the freezer room installer should be contracted to provide a maintenance service similar to that described in clause FR.29. In some countries it will not be possible to achieve the response times given in FR.29. In such cases, the clause should be modified in consultation with the installer.

ANNEX 1 - CFC-free symbol

NOTE: Include the WHO/EPI CFC-free symbol as set out in Annex 7 of WHO document WHO/EPI/LHIS/97.14 - *Equipment performance specifications and test procedures*. Scale it to be 110mm diameter as printed.

ANNEX 2 - Location details for cold room or freezer room

NOTE: Complete one worksheet for each cold room or freezer room location

UNIT REFERENCE:	

			Insert tick or number where appropriate:
1	**Location of cold room** (*Describe location. For example: 'In medical store attached to central hospital'*)		
2	**No. of storeys in building**	(including basement(s))	
3	**Location of space** (*Note: cold rooms are heavy. Floor loading should be checked by a structural engineer).*	Basement Ground floor (lowest floor in building) Ground floor above a basement or crawl space Upper floor	
4	**Floor structure** (*Note: Floors must be damp-proof and strong enough to support weight of cold room*)	Solid concrete laid directly on the ground Raised concrete floor spanning between supports Timber joists/beams spanning between supports Other (describe)	
5	**Floor finish** (*Note: a level dust-free washable surface in good condition is required*)	Cement/concrete Timber boards Ceramic or terrazzo tiles Plastic tiles Other (describe)	
6	**External wall construction**	Masonry (brick, block or stone) Steel frame with cladding Timber frame with cladding Other (describe)	
7	**External wall insulation** (*Note: Enter insulation U value)*	None Fibreglass or mineral fibre Plastic foam Other (describe)	
8	**Roof insulation thickness** (*Note: Enter insulation U value*)	Enter approximate thickness ……. mm	
9	**Finish to walls internally** (*Note: A dust-free non-combustible surface is required*)	Exposed masonry Plaster or render Plasterboard/drywall Timber boarding Other (describe)	

10	**Roof structure** (*Note: A sound roof free of leaks is required*)	Concrete Timber or steel framed pitched roof Timber or steel framed flat roof Other (describe)	☐ ☐ ☐ ☐
10a	**Roof finish** *(**Note: there are health and safety implications if the roof is clad in asbestos cement sheet)*	**Asbestos cement sheet Corrugated metal sheet Tile/slate Other fibre cement sheet Bituminous felt or asphalt Other (describe)	
11	**Ceiling finish** (*Note: A dust-free non-combustible surface is required*)	None - room open to roof space Concrete Fibreboard lining Plasterboard/drywall lining Other (describe)	☐ ☐ ☐ ☐ ☐
12	**Roof insulation**	None Fibreglass or mineral fibre Plastic foam Other (describe)	☐ ☐ ☐ ☐
13	**Roof insulation thickness**	Enter approximate thickness mm	☐
14	**Heating/air-conditioning**	Permanent heating system installed Mechanical air extract system installed Air-conditioning system installed	☐ ☐ ☐
15	**Electricity supply** (*Note: Consult the electricity supply company and/or ask an electrical engineer to check the supply*)	Volts Amps Cycles in hz Is three phase supply possible? Yes/no Voltage range: ..... to ..... volts Cycle range: . ..... to ..... hertz	☐ ☐ ☐ ☐
16	**Expected hours of supply** (*Note: Ref. clauses CR.9 and FR.9. For supply less than 16 hrs increase hold-over time.)*	24 hours per day 18-24 hours per day 12-18 hours per day 8-12 hrs per day	☐ ☐ ☐ ☐
17	**Unexpected loss of supply** (*Note: Failure frequency during expected supply hrs*)	Reliable = less than once per month Once or more a month Once or more a week Once or more a day	☐ ☐ ☐
18	**Standby generator installed** (*Note: To calculate 'adjusted kVA' reduce the rated kVA by 1% for each 100 metres the site is above sea level and by 1% for*	No Yes (give details below) - Manufacturer and model:	☐ ☐

each 5.5°C that the maximum ambient temperature is above 20°C. For example, for a site at 500 metres altitude with temperature 32°C de-rate kVA by -5% (alt) -2% (temp) = -7%)	- Petrol		
	- Diesel		
	- Rated output	kVA	
	- Adjusted for altitude and temperature	kVA	
	- Hand start		
	- Automatic start on mains failure:		

ANNEX 3- Installation and commissioning/acceptance test

NOTE: Complete one worksheet for each cold room or freezer room location

All cold rooms and all freezer rooms must conduct an on-site Quality Assurance Protocol to provide buyers with a method to determine compliance with PQS E01 through successful installation and acceptance test. To prove compliance with PQS E01 the test protocol defined in PQS E01 CR-FR-2 must be successfully completed. In future editions the test protocol will be included in this document.

SKETCH PLAN OF SITE

Draw a sketch plan of each cold room site giving room dimensions, position and sizes of doorways, position and size of windows, height of room at lowest point, position of fixed equipment (radiators, air-conditioners etc.). Provide supporting photographs if possible.